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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,225	06/09/2005	Dario Alessi	002.00250	2433

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EXAMINER	
LEE, JAE W	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
04/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,225	ALESSI ET AL.	
	Examiner	Art Unit	
	JAE W. LEE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,28-34 and 36-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26,28-34 and 36-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status

It is noted by the Examiner that there are two set of claims filed by Applicants on 12/08/2004 and 05/14/2008. It is further noted that the earlier filed set of claims (12/08/2004) is a preliminary amendment to the claims and and will be used for purposes of grouping claims for restriction.

The preliminary amendment filed on 12/08/2004 amended claims 5, 8-12,15, 16, 22-26, 28, 29, 32-34, 36-38 and 42, and canceled claims 27 and 35.

Claims 1-26, 28-34 and 36-42 are pending in the instant application.

It is noted by the Examiner that the status identifier for claim 33 is incorrect, the status identifier for claim 35 is not in a parenthetical expression, and there is no status identifier for claim 42. Applicant is reminded of the amendment practice according to 37 CFR 1.121 and it is suggested that Applicants correct this issue in the next amendment to claims.

Election/Restrictions

Claims 13 and 15-18 link(s) inventions II to XII. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 13 and 15-18.

Claims 19, 22 and 32 link(s) inventions XIII to XVI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 19, 22 and 32.

Claim 33 link(s) inventions XIX and XX. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 13 and 15-18.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-13 and 15-18, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of phosphoinositide dependent protein kinase 1 (PDK1) and a hydrophobic pocket-containing protein kinase.

Group II, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of SGK.

Group III, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of PKB.

Group IV, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of p70 S6 kinase.

Group V, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of p90 RSK.

Group VI, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of PKC isoform PKCα.

Group VII, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of PKC isoform PKCδ

Group VIII, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of PKC isoform PKCζ.

Group IX, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of PRK1.

Group X, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of PRK2.

Group XI, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of MSK1.

Group XII, claim 14, drawn to the special technical feature of a method for selecting or designing a compound for modulating the activity of MSK2.

Group XIII, claim 20, drawn to the special technical feature of a mutated protein kinase PKD1.

Group XIV, claim 21, drawn to the special technical feature of a mutated protein kinase SGK.

Group XV, claim 21, drawn to the special technical feature of a mutated protein kinase PKB.

Group XVI, claim 21, drawn to the special technical feature of a mutated protein kinase P70 S6 kinase.

Group XVII, claims 23-26, drawn to the special technical feature of a polynucleotide encoding a mutated protein kinase according to claim 19.

Group XVIII, claims 28 and 29, drawn to the special technical feature of a method of identifying a compound that modulates the protein kinase activity of a protein kinase as defined in claim 19 (for example PDK1), comprising the step of determining the effect of the compound on the protein kinase activity of, or ability of the compound to bind to a mutated protein kinase according to claim 19.

Group XIX, claims 30, 31, 34, and 36, drawn to the special technical feature of an antibody reactive with the phosphate binding pocket of PDKI or other protein kinase as defined in claim 19; or an antibody reactive with PDKI or other protein kinase as defined in claim 19 but not with the said protein kinase mutated at the phosphate binding site, or vice versa and a medicament.

Group XX, claims 34 and 36, drawn to the special technical feature of an RNA molecule compound and a medicament.

Group XXI, claims 37, drawn to the special technical feature of a method of treating a patient in need of modulation of signalling by administering a compound, a mutated protein kinase or polynucleotide.

Group XXII, claims 38-42, drawn to the special technical feature of a crystalline form of a polypeptide consisting of residues 51 to 359 of full length human PDK1 or a fusion thereof.

The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Godden et al. (Evaluation of docking strategies for virtual screening of compound databases: cAMP-dependent serine/threonine kinase as an example, Journal of Molecular Graphics and Modelling, Volume 16, Issue 3, June 1998, Pages 139-143) teach a method comprising the step of using molecular modelling means to select or design a compound that is predicted to interact with the protein kinase catalytic domain of cAMP-dependent protein kinase using programs MOE, DOCK and AMBER (see page 140), which meets the limitations of claim 1, “a method for selecting or designing a compound for modulating the activity of phosphoinositide dependent protein kinase 1 (PDKI), the method comprising the step of using molecular modelling means to select or design a compound that is predicted to interact with the protein kinase catalytic domain of PDKI, wherein a three-dimensional structure of at least a part of the protein kinase catalytic domain of PDKI is compared with a three-dimensional structure of a compound, and a compound that is predicted to interact with the said protein kinase catalytic domain is selected, wherein the three-dimensional structure of at least a part of

the protein kinase catalytic domain of PDK1 is a three-dimensional structure (or part thereof) determined for a polypeptide consisting of residues *equivalent to* residues 51 to 359 of full length human PDK1, or a fragment or fusion thereof" (emphasis added). It is noted that the 3-D structure of the catalytic domain of cAMP-dependent protein kinase taught by Godden et al. is considered to be "equivalent to" the kinase catalytic domain of PDK1. Thus, because the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof.

Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/
Examiner, Art Unit 1656

/David J. Steadman/
Primary Examiner, Art Unit 1656